

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

# PCT

Translation

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:		Date of mailing (day/month/year)      See form PCT/ISA/210
Applicant's or agent's file reference <b>C39177PC</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No. <b>PCT/EP2004/000247</b>	International filing date (day/month/year) <b>15-01-2004</b>	Priority date (day/month/year) <b>15-01-2003</b>
International Patent Classification (IPC) or both national classification and IPC <b>A61K 31/198, 31/401, 31/435, A61P 7/02, 9/00, 9/02, 9/10, 37/00, 37/08, 43/00</b>		
Applicant <b>CURACYTE CHEMISTRY GMBH</b>		

**1. This opinion contains indications relating to the following items:**

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input checked="" type="checkbox"/> | Box No. II   | Priority   |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application  |

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA/EP	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

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Box No. I

Basis of the report

1. With regard to the language, this opinion has been established on the basis of:
  - ☐ the international application in the language in which it was filed
  - ☐ the translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing
    - ☐ contained in the international application as filed
    - ☐ filed together with the international application in electronic form
    - ☐ furnished subsequently to this Authority for the purposes of search
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II

Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims, Nos. 1-26, 34-36

because:

☐ the said international application, or said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 1-26, 34-36

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☒ See Supplemental Box for further details.

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	_____	YES
	Claims	8-33, 37-45	NO
Inventive step (IS)	Claims	_____	YES
	Claims	8-33, 37-45	NO
Industrial applicability (IA)	Claims	_____	YES
	Claims	8-26	NO

2. Citations and explanations:

3. The following documents are cited:

- D1: WO 02/062829 A (HARAMURA MASAYUKI; KOGA TAKAKI (JP); SATO HARUHIKO (JP); KADONO SHOJI) 15 August 2002 (2002-08-15)
- D2: WO 02/14349 A (LEVY ODILE ESTHER; WEINHOUSE MICHAEL I (US); CORVAS INT INC (US); MAD) 21 February 2002 (2002-02-21)
- D3: KÜNZEL, S; SCHWEINITZ, A; REISSMANN, S; STUERZEBECHER, J; STEINMETZER, T: "4-Amidinobenzylamine-Based Inhibitors of Urokinase" BIOORGANIC & MEDICINAL CHEMISTRY LETTERS, OXFORD, GB, Vol. 12, 2002, pages 645-648, XP002193207 ISSN: 0960-894X
- D4: WO 03/076391 A (SCHWEINITZ ANDREA; STEINMETZER TORSTEN (DE); STUERZEBECHER JOERG (DE)) 18 September 2003 (2003-09-18)
- D5: WO 03/076457 A (SCHWEINITZ ANDREA; STEINMETZER TORSTEN (DE); STUERZEBECHER JOERG (DE)) 18 September 2003 (2003-09-18)
- D6: DE 102 12 555 A (TECH UNI MUENCHEN; UNIV SCHILLER JENA (DE)) 25 September 2003 (2003-09-25)

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

D7: STUERZEBECHER, J; PRASA, D; WIKSTROEM, P;  
VIEWEG, H: "Novel plasma kallikrein inhibitors  
of the benzamidine type" BRAZILIAN J MED BIOL  
RES, Vol. 27, 1994, pages 1929-1934,  
XP009030092

4. The compounds claimed in the present application are known as medicaments from D1-D3 (cf. the passages indicated in the search report). Therefore, only a second medical application would be admissible.

5. A main claim restricted to the second medical application of the compounds as per claim 8 for treating the medical conditions indicated in claims 27 and 28 would not be considered novel.

D1 describes the inhibiting of factor VIIa, according to which the compounds can be used as anticoagulants. See page 2, lines 5-17; claim 14.

Attention is drawn in this respect to the fact that the mechanism of action is not considered at all.

6. The PCT Contracting States do not contain uniform criteria for assessing the industrial applicability of claims 8-26 in their present form. Patentability may also depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

for a new medical application.

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Box No. VI

Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No.  
Patent No.

Publication date  
(day/month/year)

Filing date  
(day/month/year)

Priority date (valid claim)  
(day/month/year)

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day/month/year)

Date of written disclosure  
referring to non-written disclosure  
(day/month/year)

7. D4-D6 are cited pursuant to PCT Rules 64.3 and 70.10.



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Box No. VIII      Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

8.      The objections raised in the search report concerning clarity/support of claims 1-7 and 34-36 are upheld pursuant to PCT Articles 5 and 6 and Rule 6.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: III

1. The present application was only searched in part.  
Pursuant to PCT Rule 66.1(e), only the searched portion is examined, namely claims 8-33 (in part) and 37-45 (in part) - cf. form PCT/ISA/201.
2. Claims 8-26 relate to subject matter which, in the opinion of this Authority, is covered by PCT Rule 67.1(iv). A report is therefore not established into the industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(i)).